K082757

OCT 01 2008

VII. Summary of Safety and Effectiveness

Submitter's name, address, telephone number and contact person:

Bioplate, Inc.
3643 Lenawee Avenue
Los Angeles, CA, 90016
(310) 815-2100
(310) 815-2126 (fax)

Contact Person: Jesus Farinas

Trade name of Device:

Modified Sterile Plate & Screw Kit Configurations for use with the Bioplate® Titanium Fixation System.

Common Name:

Bone Fixation Plates and Bone Screws

Device Classification:

Class 2, 21 CFR 872.4760
JEY

Predicate Devices:

Sterile Plate & Screw Configurations for use with the Bioplate® Titanium Fixation System
(K022033)

Walter Lorenz instruments, Inc.
Lorenz 1.5mm Neuro Pack/Lorenz 2.0FT plates (Sterile Version)
(K972322)

Synthes (USA)
Maxillofacial Titanium Micro Set
(K912932)

TiMesh Inc.,
Softplates and Screws.
(K923419, K923802, K973145)

Techmedica, Inc.,
Anspach Fixation System
(K921801)

Walter Lorenz Surgical Instruments, Inc.,
Ultra-Micro Titanium Cranial Osteosynthesis System,
(K910038)

KLS-Martin L.P.
KLS-Martin Micro Osteosynthesis System (1.0mm)
(K944561)

KLS-Martin L.P.
KLS-Martin Micro Osteosynthesis System (1.5mm)
(K944545)

KLS-Martin L.P.
KLS-Martin Micro Osteosynthesis System (2.0mm))
(K943347)

Sofamor Danek
Timesh System
(K947017)

Hwmedica, Inc.,
Luhr Titanium Pan Fixation System
(K945139)

Description of the Device:

The Bioplate® Titanium Fixation System includes a variety of plate configurations for different anatomical applications. Unalloyed commercially pure Grade 1, Grade 2 and Grade 4 titanium and titanium alloy plates, and titanium alloy screws of varying diameters and lengths are included for fixation of the plates to the craniomaxillofacial bony tissues. These materials have been implanted safely for many years. The predicate device had been approved under K022033.

The bone plates will be manufactured of unalloyed, commercially pure titanium and titanium 6Al-4V Eli alloy. The materials adhere to the American Society of Testing and Materials (A.S.T.M.) F67 Standards and

the American Society of Testing and Materials (A.S.T.M.) F136 Standard.. The screw will be manufactured of a titanium 6Al-4V Eli alloy that meets the American Society of Testing and Materials (A.S.T.M.) F136 Standard.

The plate and screw fit configurations are sterilized by gamma radiation sterilization, using VD Max dose setting method. Successful completion of sterilization validation and packaging validation studies provides a high level of assurance that sterility of the device has been achieved and can be maintained.

Intended Use of the Device:

The sterile plate and screw kit configurations for use with the Bioplate® Titanium Fixation System are intended for use on non-load bearing fixation, including cranial bone fixation and brow fixation and the treatment of fractures and reconstructive procedures of the craniomaxillofacial skeleton. Each device is intended for single use only and only in conjunction with other titanium and titanium alloy implant.

Comparison of the device's technological characteristics with those of the predicate devices

The sterile plate and screw configurations for use with the Bioplate® Titanium Fixation System have the same indications for use as the Bioplate, Inc., Walter Lorenz, Synthes, TiMesh and KLS-Martin predicate devices. All the technical characteristics of the sterile plate and screw kit configurations for use Bioplate® Titanium Fixation System are substantially equivalent to the corresponding characteristics of the predicate devices, and any minor differences raise no new issues of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 01 2008

Mr. Jesus T. Farinas
Director, Quality Assurance/Regulatory Affairs
Bioplate, Incorporated
3643 Lenawee Avenue
Los Angeles, California 90016-4310

Re: K082757
Trade/Device Name: Modified Sterile Plate & Screw Kit Configurations for use with the Bioplate® Titanium Fixation System
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: September 15, 2008
Received: September 19, 2008

Dear Mr. Farinas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use

510(k) Number (if known) K082757

Device Name: Modified Sterile Plate & Screw Kit Configurations for use with the Bioplate® Titanium Fixation System.

Indication for Use:

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Prescription Use ____X_____ AND/OR Over-The Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of the CDRH, Office of Evaluation (ODE)

Sean Runnels

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082757